



[Billing Code: 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES
National Institutes of Health

Office of the Secretary Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Task Force on Research Specific to Pregnant Women and Lactating Women (PRGLAC) scheduled for November 6-7, 2017, in Conference Room C-D, 6001 Executive Boulevard, National Institutes of Health, Rockville, MD 20852, which was published in the Federal Register on April 18, 2017, 82 FR 18305.

The agenda for the meetings is listed below:

November 6, 2017 - Day 1

8:30 a.m.	Welcome and Opening Remarks
8:40 a.m.	Introductions
9:15 a.m.	Summary and discussion of work products from meeting 1
11:30 a.m.	Open Public Presentations
1:15 p.m.	Ethical issues surrounding the inclusion of pregnant women and lactating women in clinical research (brief presentations followed by open discussions)
4:50 p.m.	Recap of Day 1, Action Items, Charge to Group
5:00 p.m.	End of Day 1

November 7, 2017 - Day 2

8:30 a.m.	Recap from Day 1, Outline & Goals of Day 2
8:45 a.m.	Panel: Inclusion of pregnant women and lactating women in research (brief presentations followed by open discussions)
10:45 a.m.	Panel: Ethical issues of specific clinical research designs (brief presentations followed by open discussions)
1:00 p.m.	Panel: Perspectives from industry, research participants, and researchers (brief presentations followed by open discussions)
4:30 p.m.	Recap of Day 2, Action Items, Charge to Group
5:00 p.m.	End of Day 2 – ADJOURN Meeting

Public comments are welcome either by filing written comments and/or providing oral comments at the meeting. Oral comments from the public will be scheduled on November 6, 2017 from approximately 11:30 a.m. – 12:00 noon. Any member of the public interested in presenting oral comments on November 6, 2017, should submit a letter of intent, a brief description of the organization represented, and the oral presentation to Ms. Lisa Kaeser (Kaeserl@mail.nih.gov) by 5:00 p.m. on Monday October 23, 2017. Written comments to be included at the meeting should also be sent to Lisa Kaeser by 5:00 p.m. on Monday October 23, 2017. The submitted presentations and any written comments will be formatted to be posted on the PRGLAC website for the record. Only one representative of an organization may be allowed to present oral comments. Presentations will be limited to three to five minutes per speaker depending on the number of speakers to be accommodated within the allotted time. Speakers will be assigned a time to speak in the order of the date and time when their request to speak is received. Both printed and electronic copies are requested for the record.

Any changes to the meeting agenda, including tentative times, as well as other relevant additional information about the meeting will be posted on the website for the Task Force on Research Specific to Pregnant Women and Lactating Women (PRGLAC) located at: <https://www.nichd.nih.gov/about/advisory/PRGLAC/Pages/index.aspx>.

Dated: September 26, 2017.

Anna Snouffer,
Deputy Director,
Office of Federal Advisory Committee Policy.

